

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

BIOVAIL LABORATORIES INTERNATIONAL SRL )  
a corporation of Barbados, )

Plaintiff, )

v. )

ANDRX PHARMACEUTICALS, LLC and )  
ANDRX CORPORATION, )

Defendants. )

C.A. No. 05-586  
(KAJ)

**ANDRX'S MOTION TO CONSOLIDATE BIOVAIL'S TWO SEPARATE ACTIONS  
ALLEGING INFRINGEMENT OF THE SAME PATENT AGAINST THE SAME  
ANDRX DEFENDANTS**

Pursuant to Rule 42(a) of the Federal Rules of Civil Procedure, Defendants Andrx Pharmaceuticals, LLC, and Andrx Corporation (collectively "Andrx") respectfully request that the Court consolidate Civil Action No. 05-586 and Civil Action No. 05-730, both pending before Your Honor. The two separate actions were filed by Biovail Laboratories International SRL ("Biovail") within two and a half months of each other. Both allege infringement of the same patent by the same Andrx defendants, based on the same proposed Andrx drug product, albeit in different dosages (i.e. strengths).

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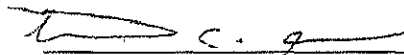
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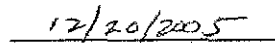
C.A. No. 05-586  
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**LOCAL RULE 7.1.1 STATEMENT FOR ANDRX'S MOTION TO CONSOLIDATE  
BIOVAIL'S TWO SEPARATE ACTIONS ALLEGING INFRINGEMENT OF THE  
SAME PATENT AGAINST THE SAME ANDRX DEFENDANTS**

In accordance with Delaware Local Rule 7.1.1, I hereby assert that counsel for Andrx made a reasonable effort to reach agreement with the opposing attorneys regarding consolidation in series of correspondences on or around November 29, December 6 and December 7, 2005. Because of our inability to reach agreement, Andrx has filed this motion.



Matthew C. Marlowe



Date

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ANDRX PHARMACEUTICALS, LLC and )

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Defendants. )

Civil Action No. 05-586-KAJ

**ORDER**

**IT IS SO ORDERED**, this \_\_\_\_\_ day of \_\_\_\_\_, 200\_, that Civil Action Number 05-730-KAJ and Civil Action Number 05-586-KAJ are consolidated and to be hereinafter referred to under Civil Action Number 05-586-KAJ.

\_\_\_\_\_  
JUDGE KENT A. JORDAN

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ANDRX PHARMACEUTICALS, LLC and )  
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Defendants. )

C.A. No. 05-586  
(KAJ)

MEMORANDUM IN SUPPORT OF ANDRX'S MOTION TO CONSOLIDATE  
BIOVAIL'S TWO SEPARATE ACTIONS ALLEGING INFRINGEMENT OF THE  
SAME PATENT AGAINST THE SAME ANDRX DEFENDANTS

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**TABLE OF AUTHORITIES**

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## **I. INTRODUCTION**

Defendants Andrx Pharmaceuticals, LLC, and Andrx Corporation (collectively “Andrx”) submit this memorandum in support of their motion to consolidate two separate actions filed by plaintiff Biovail Laboratories International SRL (“Biovail”), alleging infringement of the same patent based on Andrx’s submission of a single application to the FDA for approval to market a competitive drug product.

## **II. BACKGROUND AND FACTS**

Plaintiff filed this Hatch Waxman Act patent case on August 10, 2005, alleging infringement of U.S. Patent No. 5,529,791 (the “’791 patent”) based on Andrx’s submission to the FDA of Abbreviated New Drug Application (“ANDA”) No. 77-686, which seeks approval to sell a generic version of Biovail’s Cardizem® LA drug product. Complaint, ¶¶ 16-17. Before Andrx filed its answer in this action, Andrx gave notice that it had amended ANDA No. 77-686 to include different strengths (i.e., amounts of active ingredient in the tablet) of the same proposed drug product.

Instead of simply amending its Complaint in this action, however, Biovail chose to file a separate action on October 14, 2005, again alleging infringement of the same ’791 patent based on Andrx’s submission of the same ANDA No. 77-686, as amended. Declaration of Matthew C. Marlowe (“Marlowe Decl.”), Exh. A ¶¶ 19-20. The parties, the patent, the witnesses and the documents to be produced in both actions are the same. Indeed, *at Biovail’s request*, Andrx has provided discovery responses in this action as to all strengths of its proposed product in the ANDA as amended. *See* Marlowe Decl., Exhs. B, C.

Because these two actions are virtually identical, the Court may well wonder (a) why Biovail filed the second action instead of amending this one, and (b) why Biovail has not stipulated to consolidation of the second action with this one. The answer to both is that Biovail is attempting to (mis)use its unnecessary second action to delay the trial date set by the Court in this case. Every day that Biovail can postpone trial guarantees another day without competition,

because the Hatch Waxman Act automatically stays FDA approval of Andrx's product until final judgment or two and a half years. *See* 21 U.S.C. § 355(j)(5)(B)(iii). Accordingly, Biovail now refuses to consolidate the two actions unless Andrx agrees to delay the current trial date. *See* Marlowe Decl., Exh. D.

The cases should be consolidated and proceed under the current scheduling order.

### **III. ARGUMENT**

The Federal Rules of Civil Procedure provide that “[w]hen actions involving a common question of law and fact are pending before the court, it may order a joint hearing or trial of any or all the matters in issue in the actions; it may order all the actions consolidated; and it may make such orders concerning proceedings therein as may tend to avoid unnecessary delay.” Fed. R. Civ. P. 42(a). The two Biovail actions pending before the Court involve identical issues of law and fact, and no delay is necessary or appropriate in light of the fact that Andrx already has provided discovery with respect the additional strengths of the proposed product in the ANDA as amended. Further, Biovail, under the Hatch Waxman Act, is subject to an affirmative duty to expedite this action. 21 U.S.C. § 355(j)(5)(B)(iii).

#### **A. The Separate Actions Involve Common Issues of Law and Fact.**

Common issues of law and fact dominate these actions. In both instances, for example, Andrx relies on plaintiff's New Drug Application (“NDA”) No. 21-392 in filing its ANDA. As plaintiff pointed out in its *first* Complaint, NDA No. 21-392 includes a range of product strengths: 120, 180, 240, 300, 360 and 420 mg. *See* Complaint, ¶ 13. Those are the same strengths for which Andrx is seeking approval. Nevertheless, Biovail hopes to divide them between two separate patent cases. That these twin actions arise from the same set of facts is made clear by comparing the two complaints. They begin with the same 15 paragraphs, differ by only 3 paragraphs and request the same relief. *Compare id.* with Marlowe Decl., Exh. A.

Andrx's ANDA No. 77-686 and its ANDA No. 77-686 as amended do not differ in any material way. Andrx submitted its ANDA to gain FDA approval to sell tablets that include

diltiazem hydrochloride as their active ingredient. Andrx's amendment merely extended the range of tablet strengths proposed from 420 mg to 120 - 420 mg of diltiazem hydrochloride. In the first case, Biovail has accused Andrx of infringing the '791 patent with its proposed product at the 420 mg strength. In the second case, Biovail has accused Andrx of infringing the '791 patent with its proposed 120 mg, 180 mg, 300 mg, and 360 mg strengths. The '791 patent claims do not include any specific language regarding the dosage of infringing products beyond claiming "an effective amount" of active ingredient. *See e.g.*, '791 patent, Col. 8, ln. 57-Col. 10, ln. 11. Andrx believes that each and every strength of the product proposed in its ANDA No. 77-686 has always constituted a clinically effective amount of active ingredient.

As demonstrated in the table below, the two actions at issue involve identical parties, the identical patent, and the same Andrx Abbreviated New Drug Application ("ANDA") submitted to the FDA.

	<b>Civil Action No. 05-586</b>	<b>Civil Action No. 05-730</b>
Plaintiff	Biovail Laboratories Int'l SRL	Biovail Laboratories Int'l SRL
Defendants	Andrx Pharmaceuticals, LLC Andrx Corporation	Andrx Pharmaceuticals, LLC Andrx Corporation
Patent-in-Suit	'791 Patent	'791 Patent
Named Inventors	Arthur M. DeBoeck and Philippe R. Baudier	Arthur M. DeBoeck and Philippe R. Baudier
Accused Andrx ANDA	77-686	77-686
Drug Product	Diltiazem Hydrochloride Tablet	Diltiazem Hydrochloride Tablet

The same Andrx witnesses are relevant to the development of the product at issue in both actions. Moreover, the same plaintiff and third party witnesses are relevant in determining validity, infringement and enforceability of the '791 patent. Ultimately, the court will have to

construe the same operative language in the '791 patent in assessing infringement for all the product strengths.

Indeed, the commonality of issues of law and fact are closer in this case than in other patent cases where consolidation has been granted. For example, in *Rohm and Haas Co. v. Mobil Oil Corp.*, 525 F.Supp. 1298, 1309-10 (D. Del. 1981), two civil actions were consolidated where the first action was a declaratory judgment action challenging the validity of a Mobil Oil patent and the second action was an infringement action by Mobil Oil against Rohm & Haas alleging infringement of three other Mobil Oil patents and including a counterclaim alleging that Mobil Oil infringed three different Rohm and Haas patents. In the instant case, both actions allege infringement of the same patent. Moreover, the parties in both actions here are identical, as they were in the *Rohm and Haas* case. See also *Honeywell Int'l Inc. v. Audiovox Comms. Corp.*, 2005 WL 2465898, at \*3 (D. Del. May 18, 2005) (Jordan, J.) (consolidating cases against manufacturer defendants due to common questions of law and fact pertaining to infringement).

**B. Judicial Economy Is Best Served By Consolidating These Two Actions.**

Given the overwhelming evidence of commonality of law and fact here, Andrx submits that judicial economy will be best served by consolidation.

With consolidation, the Court will have to educate itself only once regarding the relevant scientific and technical subjects at issue. As the *Rohm and Haas* court recognized, "[t]here is little logic in forcing the Court to educate itself on the intricate factual details and complex legal issues common to both suits on two occasions, in preparation for two separate trials." *Rohm and Haas*, 525 F.Supp. at 1310. The technological issues between these two actions focus on the definition or role of wetting agents and surfactants in pharmaceutical tablets. The resolution of those issues in one action entirely resolves the second action.

There will be no delay in the current schedule with consolidation. In the first filed case, Andrx has already agreed to produce documents relating to all strengths of its proposed diltiazem hydrochloride drug product on an expedited basis. Furthermore, both cases are at early stages

with document production only beginning and no depositions having been scheduled. Because consolidation will not cause any delay in the first filed case, Andrx submits that the second filed action should be consolidated with the first filed action under the same schedule.

If the Court consolidates these actions, it will not have to commit its limited resources to two separate, nearly identical proceedings. Holding two separate trials merely because there is more than one strength of a product described in Andrx's ANDA "raises the specter of inefficient and wasteful duplication" especially given the large number of identical witnesses, documentary evidence and exhibits and the fact that the difference among the product's strengths is trivial relative to the '791 patent. *Id.* Judicial economy is best served by consolidating these duplicative actions.

**C. The Balance of Time Savings and Effort Outweighs Any Inconvenience, Delay, or Expense That Might Result.**

As the *Rohm and Haas* case recognized, the Court must balance the time and effort savings of consolidation against inconvenience, delay or expense that might result from consolidation. *Rohm and Haas*, 525 F.Supp. at 1310. No inconvenience, delay or expense will result from consolidation.

From Andrx's perspective, inconvenience, delay or expense would result here not from consolidation, but from a failure to timely consolidate. Andrx, the generic drug maker in these twin actions, has the stronger interest in bringing this dispute to a swift resolution and would be more inconvenienced by delay. The statute governing this case was written to expedite the resolution of patent controversies and facilitate the introduction of generic drugs into the U.S. market. That same statute effectively enjoins the FDA from approving a generic drug that has been accused of infringement until the earlier of the expiration of the 30 month statutory stay or the resolution of one of the actions now pending before this Court. 21 U.S.C. § 355(j)(5)(B)(iii). Therefore, any delay, if there is one, forces the generic drug company to continue to pay the costs of litigation while preventing that company from benefiting from any sale of its proposed

product. On the other hand, any delay allows a plaintiff, here Biovail, to reap the rewards of monopolistic pricing – whether or not the generic drug actually infringes a valid and enforceable patent. Andrx does not understand how Biovail could fairly claim prejudice or inconvenience by reason of consolidation and Biovail has not presented any good faith explanation as to why this would be so.

Biovail will not be legitimately inconvenienced or burdened by consolidation. It has already demanded that Andrx produce materials for all strengths of the proposed product in the first case. In its Response to Biovail's First Set of Requests for Documents and Things, Andrx has already committed to providing documents that include information about all the strengths in that product. Marlowe Decl., Exh. C. Consolidation will only deprive Biovail of its ability to continue to prolong this entire controversy. Up to now, Biovail has refused to offer any good faith explanation for why it "is not now in a position to make that commitment" on consolidation. Marlowe Decl., Exh. D. If Biovail succeeds in delaying a decision on consolidation until a Scheduling Order issues in the second filed case, it would then be in a position to fight for the schedule that it believes is most advantageous. Moreover, if it staves off consolidation, Biovail can bolster its opportunity to argue for prejudice and, therefore, an extension of the current schedule. That would be a prejudice of its own making.

#### **IV. CONCLUSION**

For the foregoing reasons, Andrx respectfully requests that Civil Action No. 05-586 and Civil Action No. 05-730, both already pending before Your Honor, be consolidated and litigated under the current scheduling order.

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